UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	[FILED UNDER SEAL PURSUANT TO COURT ORDER]

SUPPLEMENTAL DECLARATION OF SUMANTH ADDANKI, PH.D.

April 27, 2006

[REDACTED VERSION]

I. Introduction

A. Assignment

1. I am an economist and a Senior Vice President at NERA Economic Consulting. Earlier in this proceeding, I submitted "Declaration of Sumanth Addanki, Ph.D." dated March 15, 2006. Counsel for Schering-Plough and Warrick have asked me to review "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment" dated April 6, 2006 and apparently written in reply to my declaration as well as other submissions by the defendants. In it, he offers several responses to my declaration, while also offering various additional views. I comment briefly on his latest Declaration here.

B. Summary of Conclusions

2. In brief, my conclusions are as follows:

- Dr. Hartman proclaims that he never intended that AWP equals ASP. In fact, his entire approach to calculating damages under Medicare Part B implicitly does precisely that.
- Confronted with the evidence that "spreads" very much on the order of his so-called "mega-spreads" were known to exist in publicly available documents, he resorts to a sequence of arguments-in-the-alternative as to why this evidence is irrelevant, none of which is ultimately persuasive.
- He introduces in this declaration a theory of coordinated behavior that has never been broached before by him or his client; perhaps mindful of the drastic change that this represents, he attempts to cloak it in meaningless jargon, referring to a so-called "tacit Nash equilibrium."[1]
- In other instances, he either misstates or misunderstands my criticism and, thereby, fails to address its seriousness.

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[1] See, e.g., "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 22.

3. In what follows, I will attempt to deal with each of these in turn. Where his protestations are inconsistent with one another, I will endeavor to point that out as well.

II. AWP, EAC and ASP

A. My Criticism and Dr. Hartman's Response

4. I pointed out in my declaration the absurd results that stem from Dr. Hartman's requirement that AWP equal ASP.[2] Dr. Hartman now says that he has imposed no such requirement. However, as Judge Saris's opinion recognizes Dr. Hartman has, from the outset, expressed his view that the "but for" spread between AWP and ASP was zero for reimbursement under Medicare Part B.[3] This is nothing other than a requirement that AWP for the accused products be equal to actual ASP. According to Dr. Hartman, he establishes liability when a drug's AWP exceeds its ASP by more than 30 percent and then calculates damages "according to the Medicare Statutes" i.e., as the "amount by which the AWP … exceeds EAC = ASP."[4] Thus, Dr. Hartman says, he is misunderstood and has "**never taken the position** that Defendants should have **set the 'AWP equal to the ASP.'**"[5]

B. His Damages Methodology Implies AWP Equals ASP

5. Dr. Hartman's "30 percent screen" is nothing more than a fig leaf with which he attempts to conceal his implicit but absolute requirement that AWP equals ASP for the accused drugs.

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[2] "Declaration of Sumanth Addanki, Ph.D.," March 15, 2006, pp. 8-11.

[3] "Memorandum and Order Re: Motion for Class Certification," August 16, 2005, p. 88 ("Under Medicare Part B, he calculates the but-for spread as 0% because it is set by law.")

[4] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 5.

[5] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 4 (emphasis in original).

6. To claim that he calculates damages "according to the Medicare Statutes" is simply meaningless: Medicare does not specify statutory damages. Rather, damages are calculated here as in any other such context: the damage to the plaintiff is the difference between what it paid in the real world and what it would have paid in the world ***but for*** the alleged wrongdoing.[6] A forensic economist of Dr. Hartman's apparent experience should be well versed in this basic principle.[7]

7. What does this fundamental principle imply in the context of Medicare Part B reimbursement in this case? Because Dr. Hartman's initial liability screen is a 30 percent "spread," in order to avoid liability under this screen a drug's AWP had to be within 30 percent of its ASP. Therefore, in the "but for" world, AWP could have been as high as 30 percent above ASP. The appropriate measure of damages ***consistent with Dr. Hartman's liability test*** is simply the difference between reimbursement based on the actual AWP and reimbursement based on this "but for" AWP (which is 30 percent ***above*** ASP). But Dr. Hartman, of course, does not compute damages in this manner. Rather, he asserts through his damages calculations that the "but for" reimbursement rate would have been at ASP.[8]

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[6] See, e.g., Antitrust Practice Guide of the Section of Antitrust Law of the American Bar Association, *Proving Antitrust Damages: Legal and Economic Issues*, 1996, p. 36 ("Whatever the index of the harm to the plaintiff from an antitrust violation, the measure of antitrust damages is the difference between (1) the plaintiff's situation *given* the violation has occurred (its actual condition) and (2) the plaintiff's situation in a hypothetical world in which the violation has not occurred but conditions are otherwise the same (its 'but for' condition)") (emphasis in original).

[7] See, e.g., Hartman, Raymond S. and Michael J. Doane, "The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints," *Journal of Law, Economics, and Organization*, 1987, p. 369 ("The difference between what they actually paid and what they would have paid is the loss in value incurred at the time of purchase").

[8] See, e.g., "Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calcu[l]ation of Damages," December 15, 2005, Attachment J.6 ("Damages formula from 1991 to 2003: ((1-x%) * AWP – ASP * Units * Medicare Share") and "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 5. See also, "Memorandum and Order Re: Motion for Class Certification," August 16, 2005, p. 88, n. 27 ("[Dr. Hartman] identifies the yardsticks--the percentage amounts that TPPs believe ASPs are below AWPs--in the PBM context as being 16% to 33% for single source drugs, and

(continued...)

8. Now, there are only two ways in which that could have been true in the "but for" world. Either (1) the drugs were being reimbursed at AWP, and the "but for" AWP was set at ASP, or (2) Medicare chose to reimburse using EAC, and the EAC happened to equal ASP. As I will discuss below, there is no reason to expect EAC to equal ASP, but, much more important, there is absolutely no basis to assert even that Medicare would have reimbursed these drugs using EAC. It is widely known—and Dr. Hartman does not contest—that EAC was not, in fact, used. Rather, reimbursement was based on AWP.[9] There is absolutely no reason why, in a "but for" world in which the accused drugs' AWPs were within 30 percent of ASP—Dr. Hartman's so-called liability test—HCFA or Medicare would have singled out the accused drugs for reimbursement under a different formula, an outcome that even Dr. Hartman concedes is unlikely.[10] Thus,

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(...continued)

10% to 20% for multiple source drugs, and in the physician-administered context as being 0% for Medicare and 18% to 33% for the private drugs. (Hartman Decl. ¶ 33.)").

[9] Department of Health & Human Services, Office of the Inspector General, "Excessive Medicare Payments for Prescription Drugs," 1997, p. 1 ("Historically, carriers have utilized AWP and not estimated acquisition cost to develop Medicare reimbursement for prescription drugs.") See also "Memorandum and Order Re: Motion for Class Certification," August 16, 2005 p. 70 ("The EAC was supposed to be measured through surveys conducted by regional Medicare administrators (termed "carriers"), who were to determine the usual and customary charge ("U & C") for a geographic area. [42 C.F.R. § 405.517 (amended Nov. 2, 1998; Jan. 7, 2004; Nov. 15, 2004)]. However, the carriers never conducted the surveys, and instead relied on AWPs. (Rosenthal 7) … Because the carriers never conducted the surveys of EACs, AWP became the basis for most Medicare reimbursement. (Rosenthal 7)".

[10] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 10 ("Medicare would not alter their reimbursement practices based upon a single generic Part B drug or on several multi-source generic drugs beginning to be cited in 1996.") Dr. Hartman does assert, on one occasion, that had Medicare been aware of the magnitude of these "spreads," it would have hastened to carry out the EAC surveys and would, therefore, have reimbursed at EAC. "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 5 ("The assumption underlying this method is that had HCFA and Medicare understood sufficiently the general extent to which the actual "spreads" on physician administered drugs were *mega-spreads*, they would have more aggressively undertaken the surveys to calculate EACs and impose the lesser of AWP (or a percent thereof) and the EAC practice for reimbursement") (emphasis in original). This argument is preposterous, for at least two reasons. First, in the ***but for*** world, which is the world whose reimbursement rate is at issue, the "spreads" that Dr. Hartman finds objectionable would not have existed, so there would have been no heightened motivation to survey EACs in the manner he suggests. Second, and as important, there is ample evidence that Medicare knew, or should have known, about these "spreads," as discussed further below.

reimbursement would have continued at the (lower) "but for" AWP, but NOT at ASP as calculated by Dr. Hartman, ***unless and only unless*** AWP were required to equal ASP.

C. The Use of ASP is Entirely Misplaced

9. Dr. Hartman further confounds issues by insisting, that "EAC = ASP."[11] I have already pointed out that in the "but for" world, reimbursement would have been based on a reduced AWP and NOT at some notional EAC. But of course, Dr. Hartman has never computed an EAC. Rather, he makes the peculiar assertion that EAC equals ASP. Again, following the reasoning provided at length in my declaration, EAC cannot equal ASP as a general matter.[12] EAC is meant to estimate the cost incurred by physicians in acquiring the drug. ASP is the net price actually received, by manufacturers, for their drugs. Apart from the rare case where the provider obtains the drug directly from the manufacturer, the latter's selling price will NOT equal the former's acquisition cost, unless wholesalers or other intermediaries are willing to provide their intermediation at no charge, which is, of course, contrary to basic economics.

10. This fundamental point appears to have been missed altogether in Dr. Hartman's response. Providers' acquisition costs will NOT in general equal ASP; they are prices at two different levels of the distribution chain. The latter, in general, represents what a manufacturer receives from the wholesale level of the chain, whereas the former represents what providers—the penultimate stage in the distribution chain—pay to obtain the drug. Therefore, "EAC" will exceed ASP, so the use of ASP is entirely misplaced even if "EAC" were the appropriate "but for" reimbursement rate, which it is not.

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[11] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 5.

[12] "Declaration of Sumanth Addanki, Ph.D.," March 15, 2006, pp. 8-11.

III. What Medicare Knew

A. My Criticism

11. In my declaration, I pointed to a substantial body of public knowledge—found in government publications as well as in commentaries by industry observers and participants—which made it clear that very substantial "spreads" existed between the AWPs and prices received in the distribution chain of many drugs, including Warrick's albuterol sulfate.[13] As the essence of any theory of manipulation of the "spread" must be that the perpetrator successfully concealed the true magnitude of the "spread," the question of what the government and other payors—the market participants of interest—knew or should have known is of paramount importance. The publications that I cite reveal that there was substantial publicly available information about the true "spreads."

B. Dr. Hartman's Response

12. Dr. Hartman does not dispute the evidence that there was public knowledge that "spreads" very much in the range of his "mega-spreads" were known to exist over the alleged damages period.[14] Rather, he attempts to minimize its lethal impact on the plaintiff's case. First, he asserts that the sources that I cite do not contain "spreads" for "single-source physician-administered drugs" that were "excessive," i.e., presumably, outside the range of his liability screen.[15] Second, he asserts that, even if Medicare had known about large "spreads" for some drugs, that would not have been sufficient to

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[13] "Declaration of Sumanth Addanki, Ph.D.," March 15, 2006, pp. 15-16 and n. 16.

[14] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, pp. 9-10.

[15] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 9.

cause the agency to alter its reimbursement practices.[16] Both of these assertions miss the point of my criticism and of the evidence I adduced.

C. The Single Source Yardstick is a Red Herring

13. While Dr. Hartman is captivated with his "single-source" yardstick for "spreads," it remains a red herring for purposes of assessing what was known or knowable about the likely "spreads" on the larger group of drugs at issue in this lawsuit. The range of "spreads" for single source drugs is of no significance—setting aside Dr. Hartman's preoccupation with it—for those purposes. Rather, if there is a claim that the AWP of albuterol was manipulated, the relevant question is, what was known or knowable about the "spread" for albuterol or like drugs? Likewise, if there is a claim that the AWPs of physician-administered oncology drugs were manipulated, the relevant question is, what was known or knowable about the "spreads" for reasonable benchmarks for those drugs? If there was public knowledge available to industry participants that those "spreads" ranged outside the "liability yardstick" arbitrarily imposed by Dr. Hartman, a theory of manipulation fails. Limiting the question to knowledge about "single-source" drugs serves no purpose except where the manipulation is alleged to affect only such drugs. Thus, Dr. Hartman's protestation that the public data that I cite contains "spreads" on "single-source" drugs that are in the range of his liability yardstick is nothing more than the most transparent misdirection. It is simply irrelevant to the question of whether manipulation could meaningfully be said to have occurred under the circumstances of this case.

D. The "Tolerance" Argument is Irrelevant

14. Apparently in the alternative, Dr. Hartman argues that there is no particular significance to the publicly available information on "spreads" for products such as albuterol

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[16] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 10.

because, by themselves, these products were not of sufficient magnitude to cause Medicare to change its reimbursement policies.[17] He goes on to assert—whether as yet another alternative or merely as embellishment—that Medicare could not have been aware of the magnitude of "spreads" or it would not have "allowed itself to be economically injured to the extent it was in the Lupron and Zoladex matters."[18]

15. This reasoning is, at a minimum, irrelevant. If Medicare knew about the "spreads" on albuterol and chose not to act on them (during a period, it is worth remembering, in which the alternative of estimating provider acquisition costs was always open to the agency), that is Medicare's business. It may not have been cost effective for Medicare to survey providers or their suppliers, but that has nothing whatsoever to do with the question of whether the AWP of albuterol was being manipulated in any meaningful way. Rather, manipulation, by its nature, requires that the magnitude of the artificiality of the allegedly manipulated quantity be concealed. Certainly, the evidence that I have adduced indicates, clearly, that the range of "spreads" in publicly available documents and studies went far outside the liability thresholds arbitrarily espoused by Dr. Hartman and, indeed, move well into his "mega-spread" territory. In light of this evidence, it is clear that Medicare knew, or should have known from publicly available data, that "spreads" on many of the accused drugs did, in fact, range widely. No meaningful manipulation can be said to have taken place under these circumstances.

16. The suggestion that it is "impossible to explain" why Medicare allowed itself to be "economically injured" to the extent that it was on Lupron and Zolodex ignores the

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[17] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 10 ("It is this toleration that Defendants have exploited by their AWP inflation scheme.")

[18] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 10.

realities of reimbursement under Medicare.[19] Simply put, it is well recognized that the Medicare program under-compensates physicians for many of the services that they provide. For example, HCFA concluded in 2000 that Medicare under-compensated physicians for their provision of drug administration services and that drug payments above physicians' acquisition costs were offsetting these shortfalls, making it economically feasible for physicians to continue to offer such services in their offices.[20]

17. What this implies, of course, is that it is meaningless to speak of "but-for" reimbursement rates for these drugs in a vacuum. If the reimbursement rates for the drugs are lowered, unless other compensation rates for administration services are raised correspondingly, physicians will have less incentive to continue to provide these services in-office. This is a matter of simple economics: if the payment for a service falls short of the opportunity cost of providing it (i.e., the revenue that could be garnered from the best alternative use of the physician's time and facilities), the physician will cease to offer that service. Should this happen, more patients will have to travel to hospitals for such treatment in their outpatient departments, resulting in higher costs to the Medicare system, and higher co-payments by the patients as well as increased inconvenience, travel time, treatment time and the like.[21]

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[19] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 10.

[20] "Reform of the Medicare Payment Methods for Cancer Chemotherapy," American Society of Clinical Oncology, May 2001, p. 10, ("It was not until 2000 that HCFA acknowledged for the first time that Medicare payments for chemotherapy administration are too low. HCFA also concluded that its efforts to reduce drug payments should be suspended until the administration payments were increased.")

[21] "Reform of the Medicare Payment Methods for Cancer Chemotherapy," American Society of Clinical Oncology, May 2001, p. 10, ("In 1991, when HCFA proposed to reduce drug payments to 85 percent of AWP, many of the comments opposing the reduction cited the 'shortfalls in chemotherapy administration payments' and warned that '[w]ithout adequate compensation…many physicians would perform the service in hospital outpatient departments at substantially higher costs.'")

18. If, on the other hand, Medicare were to offset the reduced drug reimbursement rates by increasing its compensation for the administrative services involved, the effect would be similar: Medicare payments and beneficiary co-payments for the drugs might be lowered, but payments and co-payments for the provision of the associated services would be increased; the net result cannot be predicted without considerably more analysis.[22]

19. Thus, these realities confronting Medicare make it all too clear why the program may have chosen to continue to "overcompensate" for physician-administered drugs, even in the face of substantial knowledge about the magnitude of that "overcompensation."

IV. The Implausibility of AWP Manipulation for Generic Drugs

A. My Criticism

20. I remarked in my earlier declaration that the theory of AWP manipulation was downright implausible as a matter of economics for generic and other multi-sourced drugs.[23] That is because, I noted, reimbursement under Medicare for each drug was tied to the median AWP for the set of drugs at issue rather than each individual drug's AWP. No individual manufacturer has any incentive to inflate its AWP in this context, because its product would not be more attractive, relative to the alternatives, because of the higher AWP. Why? Because all the competing products would be reimbursed at the same rate, the median AWP. Thus, even if a manufacturer were capable of manipulating the median AWP—a feat that would be singularly difficult to achieve, as I

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[22] In fact, when Medicare did lower the reimbursement rate for prescription drugs effective January 1, 2005, they increased the dispensing fee paid to providers, in addition to adding furnishing and supplying fees. Federal Register, August 8, 2005, pp. 45846-48.

[23] "Declaration of Sumanth Addanki, Ph.D.," March 15, 2006, pp, 19-21.

pointed out—there would simply be no incentive to do so, because it would provide no competitive advantage to the manufacturer.[24]

B. Dr. Hartman's Response

21. Dr. Hartman's response is as follows. To begin with, he argues, remarkably, that the plaintiff's theory is not one of AWP manipulation but one of "spread" manipulation and avers that my analysis of AWP manipulation is, therefore, misplaced.[25] He then makes much ado about showing that the Warrick AWP for albuterol is at the median AWP (according to his calculations) "in many cases" and that this somehow contradicts my opinion (which he cites explicitly) that Warrick's AWP was generally "at or below the median."[26] Finally, Dr. Hartman, conceding in so many words that no individual generic manufacturer has an incentive to inflate its AWP, now attempts to articulate an entirely new theory, one that is fundamentally contrary to the plaintiffs' theories to date: that AWPs were inflated because manufacturers had a shared incentive in assuring that their products earned higher reimbursement rates.[27]

C. Manipulation of AWPs or "Spreads?"

22. To begin with, the plaintiffs—and Dr. Hartman himself—have repeatedly referred to the "AWP manipulation scheme" that I analyzed. Indeed, the case caption speaks for itself in that regard. Purely by way of illustration, I have furnished, in Appendix A, selected citations from the plaintiffs' documents—including the latest Hartman declaration—that explicitly refer to a scheme to manipulate or inflate AWPs. Thus, it is simply untrue to aver that the plaintiffs' case is not about the manipulation of AWP.

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[24] "Declaration of Sumanth Addanki, Ph.D.," March 15, 2006, pp, 19-21.

[25] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 18.

[26] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 21 and n. 49.

23. In any event, even if the plaintiffs' case had been expressed throughout purely as one of "spread" manipulation—which it has not—there can be little doubt that any theory of "spread" manipulation must, ultimately, resolve itself into a theory of AWP manipulation. Why is this? Simply because the "spread" calculated by Dr. Hartman is just the difference between the AWP and the ASP. Increases in this "spread" are the result of increases in the AWP or reductions in ASP. Reductions in ASP are nothing more than price competition—the very foundation stone of U.S. antitrust policy and law; presumably Dr. Hartman does not object to price competition. Therefore, the only way in which "spreads" as calculated by Dr. Hartman could be inflated is if the AWPs underlying them were inflated. In other words, the plaintiffs' theory is, indeed, a theory of AWP inflation.

D. Warrick's Albuterol "Spreads"

24. Dr. Hartman appears much exercised about my analysis of the AWPs for albuterol sulfate. Based on my analysis of AWP data, I concluded that Warrick's AWPs were generally at or below the median for the group despite Warrick enjoying relatively large market shares, that Warrick's AWPs were not raised in response to the entry of products (i.e., Nephron) that succeeded in taking share away from Warrick's products and, indeed, that Warrick's AWPs had remained constant since 1995.[28] All of these points, I noted, were entirely inconsistent with the plaintiff's theory of generic AWP manipulation but served, instead, to reinforce my explanation of why that theory was implausible.

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[27] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 21.

[28] "Declaration of Sumanth Addanki, Ph.D.," March 15, 2006, pp. 21-24 and Exhibits.

25. Dr. Hartman expends considerable time and energy in tinkering in various ways with the data underlying my analysis—and which I included in my declaration. For instance, he suggests that, under the relevant regulations, three of Xactdose's 0.5% products should not be included in the calculation of the median.[29] He also suggests that the Medispan data for a Major 0.083% product contains an error and that the AWP there is overstated.[30] What makes Dr. Hartman's preoccupation with these data issues particularly mystifying, however, is that they make no material difference to the conclusions! Even excluding the Xactdose products, adopting his adjustments to the AWP for the Major product, and recalculating a median AWP does not alter the points that I made in my declaration: Warrick's AWPs for albuterol 0.5% and 0.083% were: (1) at the "lower end of the range of AWPs" and (2) were "generally at or below the median."[31] Both of these observations still hold.

26. And, although Dr. Hartman appears to find great significance in Warrick's AWP being sometimes at the median, he does not (and cannot) point to any evidence that Warrick attempted to change the median by "manipulating" its AWP. Thus, all of my conclusions stand, undisturbed by his elaborate reconfiguration of my original analysis.

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[29] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 19, n. 48 and Notes to Attachment E.

[30] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, Notes to Attachment E. In evaluating these suggestions, it is important to keep in mind what Dr. Berndt has pointed out, that determining the crosswalk between the precise list of products by NDC that were used historically to determine the median AWP and a particular J-Code is inherently difficult and may not be possible. See Professor Ernst R. Berndt, Memorandum to Judge Patti B. Saris, RE: Pharmaceutical Average Wholesale Price Litigation (M.D.L. No. 1456, Civil Action No. 01-12257-PBS) Follow-Up, p. 3 ("Whether the crosswalking will be sufficiently reliable and comprehensive in the class certification context remains I think an open empirical question.") Finally, Dr. Hartman suggests that repackagers in general should be excluded. There is no basis for such an exclusion; certainly, the regulations relating to the calculation of the median do not stipulate that they be excluded, and his suggestion that the "analysis of strategic AWP-pricing behavior of manufacturers of bioequivalent formulations should focus on those generic presentations that are not repacked or unit-dosed" has no bearing whatsoever on the manner in which reimbursement was actually carried out. See "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 33.

E. Coordination or Competition?

27. Dr. Hartman concedes expressly that no individual generic manufacturer has any incentive to inflate its AWP.[32] But, in what is arguably the most remarkable portion of his Declaration, and in a complete departure from the plaintiffs' theories of the case, Dr. Hartman seems to suggest, rather, that the AWP inflation involved a collusive scheme on the part of Defendants, and perhaps others. According to him, "it is true all generic manufacturers of a given drug have the incentive to maintain the median AWP as high as possible, in order to increase the "spreads" of all manufacturers relative to potential alternative therapeutic competitors."[33] He also refers to the observed AWPs as being a "tacit Nash equilibrium." It may be useful to debunk any misimpression created by this unnecessary misuse of economic jargon. In the simplest terms, a Nash equilibrium is just a state of affairs in which no participant has any incentive to modify his or her behavior given the behavior of every other participant. Therefore, calling a given marketplace outcome a Nash equilibrium is merely stating the obvious; **any** sustainable marketplace outcome is such an equilibrium. And, the use of the emotive word "tacit" adds no further meaning to this. To the extent that Dr. Hartman's musings are of any relevance whatsoever, it can only be because of a suggestion that the observed outcome is a Nash equilibrium that arose from tacit **collusion** rather than from competitive forces. Apparently the plaintiffs, at this stage, seek to enunciate a theory of collusive

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[31] "Declaration of Sumanth Addanki, Ph.D.," March 15, 2006, pp. 17 and 21.

[32] See. e.g., "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, pp. 21 and 33.

[33] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 33.

behavior regarding AWPs, despite Judge Saris's view that the plaintiffs' "key" allegation was that manufacturers compete rather than conspire with each other.[34]

1. Tacit Collusion is an Unlikely Explanation for the Observed Behavior

28. The AWP data that I have seen—as well as marketplace realities—are inconsistent with the observed outcomes being the result of tacit collusion. The economic underpinnings of any theory of tacit collusion are well known: the parties must be able to tacitly agree readily on an appropriate level for AWP; the parties must be able to tacitly agree readily on the degree to which deviations from the agreed price will be deemed permissible; and, there must be an effective way to accomplish targeted punishment of such deviations.[35] None of those conditions are met here.

29. To begin with the parties must agree that elevated AWPs are in their common best interest. Dr. Hartman appears simply to assume that this is the case. In fact, it is not. Certainly, products like albuterol which are prescribed by physicians and dispensed by pharmacies present no particular incentive for their manufacturers to seek higher AWPs. Higher AWPs do not exert economic influence over prescribing decisions for albuterol, as I have already explained. Higher AWPs do not benefit any one generic manufacturer at the expense of the others.

30. Even in the case of products prescribed and dispensed by physicians, generic manufacturers' incentives are neither self-evident nor necessarily aligned across manufacturers. Even if AWPs were elevated with a view towards shifting share from

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[34] "Memorandum and Order Re: Motion for Class Certification," August 16, 2005 p. 94, ("the key allegation in the SAMCC is that pharmaceutical companies compete (not conspire) with one another for market share by boosting the AWP of competitive drugs or offering rebates.")

[35] U.S. Department of Justice and the Federal Trade Commission, *Horizontal Merger Guidelines* (1992, revised 1997) § 2.1 ("Successful coordinated interaction entails reaching terms of coordination that are profitable to the firms involved and an ability to detect and punish deviations that would undermine the coordinated interaction.")

therapeutic substitutes, it is by no means clear that all—or even most—of the generic manufacturers of the molecule would regard that with equal favor.[36] Among other things, their attitude towards such share diversion would depend upon their economic interest in those therapeutic substitutes. In light of this, it is inherently implausible to suggest that generic manufacturers could tacitly agree on the appropriate AWPs for a given molecule.

31. Moreover, as an empirical matter, the AWPs for a given product span a range; it is difficult to visualize a collusive scheme that permits a range of prices, because it is then intrinsically unclear whether a particular AWP is within or outside the "permissible" range and who, among the alleged tacit conspirators, will make that determination. It is even more difficult to visualize a method of targeted punishment of violations, assuming that the parties could even agree upon what constitutes a violation—and assuming they could overcome the inherent difficulties in changing a median value. What form might the punishment take and who bears the cost of imposing it? Without effective means of policing the putative agreement, tacit collusion is inherently untenable.

2. Proventil and the Role of Branded Drugs in Dr. Hartman's New Theory

32. Dr. Hartman further opines that the set of AWPs for generic drugs "are themselves all artificially inflated to the extent that the branded AWP against which the generic AWPs are set, is artificially inflated."[37] While it is true that generic AWPs are set in reference to branded AWPs, Dr. Hartman's suggestion that albuterol AWPs are high because they were set in reference to an artificially inflated Proventil AWP has no basis in fact or

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[36] Of course, all of this remains purely hypothetical; Dr. Hartman has yet to furnish any analysis showing that such therapeutic substitution could even be realistic for any of the products at issue.

[37] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 33; see also pp. 21-22.

logic, in large part because there is no basis to suppose that Proventil's AWP was artificially inflated in the first instance. Finally, it would have been economically irrational for Schering to lower its list price (i.e., its WAC and AWP)—quite apart from any AWP "manipulation"—because a very sizeable proportion of Proventil sales (about 60 percent) were made at or near list price.[38] See Exhibit 1.

33. That is because, even though it is reimbursed under Medicare Part B, Proventil is a self-administered drug purchased at pharmacies. Inflating its AWP makes no difference to physicians' economic incentives to prescribe it, so Schering had no economic incentive to engage in such inflation. Moreover, Proventil was in competition with other branded albuterol drugs, Ventolin and Airet, and Dr. Hartman himself concedes that "all drug manufacturers, particularly innovator drug manufacturers, use [list prices as signals] to strategically place drug products in the market."[39] Thus, it was the competition between these branded products that would have set Proventil's pricing, not any AWP inflation scheme of the sort suggested by Dr. Hartman.

V. Conclusion

34. Although Dr. Hartman expresses vehement objections and provides lengthy responses to my criticisms of his approach and conclusions, these objections and responses either miss the point of my criticism or simply leave them unchanged, or both.

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[38] The WAC represents the closest thing to a "list price" in the branded pharmaceutical industry. While many customers are able to negotiate discounts, as noted above, a non-trivial portion of sales are actually made at or very near list price. For instance, I have calculated that about 78 percent of Schering's sales of branded pharmaceutical products in the year 1999 were made at prices within two percent of WAC.

[39] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 28.

Sumanth Addanki, Ph.D.

4-27-06

Date

EXHIBIT 1

FILED UNDER SEAL

APPENDIX A

Dr. Hartman, Dr. Rosenthal and the plaintiffs repeatedly refer to the alleged manipulation and inflation by the defendants of AWP. Dr. Hartman does so in this most recent declaration.

See, e.g.,

- "The AWP scheme at issue involved artificially inflating the list price of the relevant drugs (AWP, and by implication any list price and any end-payer reimbursement rate formulaically linked to AWP) while reducing the actual acquisition cost of the drugs to the relevant provider, thereby increasing the spread earned by the provider of drugs."[1]

- "At ¶ 8 of that same September 3, 2004 Declaration in Support of Class Certification, I state:

  > 'This scheme or course of conduct [in this litigation] is alleged to have been effectuated as follows. Defendant Drug Manufacturers artificially inflated the AWPs of their relevant drug products, which in turn increased and inflated the reimbursement rates earned by the market entities capable of 'moving market share' – distributors, intermediaries (PBMs) and/or providers – since reimbursement rates are formulaically related to AWP (or its equivalent, the Wholesale Acquisition Cost or WAC).'"[2]

Examples from other documents include:

- "In my analysis, I have investigated … the economic incentives for manufacturers to inflate AWPs and for health care providers to select therapies with inflated AWPs."[3]

- "Manufacturers, in turn, could increase their unit sales not only by discounting their products, but also by raising their reported AWPs. Moreover, raising the AWP would be the more profitable strategy in that it could be expected to increase the number of units sold, but would have no negative impact on the manufacturers' profit margins."[4]

- "But the unique and perverse feature of this market is that pharmaceutical manufacturers can also increase market share through raising their AWP, since this list price is the basis for

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[1] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 18.

[2] "Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment," April 6, 2006, p. 31.

[3] "Average Wholesale Price Litigation Liability Report of Dr. Meredith Rosenthal," December 15, 2005, p. 1.

[4] "Average Wholesale Price Litigation Liability Report of Dr. Meredith Rosenthal," December 15, 2005, p. 6.

third-party reimbursement. Unlike offering big discounts to physicians, raising the AWP relative to the acquisition cost to the physician does not reduce profit margins on the drug in question."[5]

- "In summary, examination of the patterns of the list (AWP) and transaction (ASP) prices over time found in Defendants data provide strong support for the theory that AWP inflation was a deliberate competitive strategy. In particular, many AWPs were consistently increased by the Defendants' over the period, even while ASPs were flat or decreasing."[6]

- "And, the OIG rejected the notion that purposeful AWP manipulation was a lawful practice: … If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the antikickback statute is implicated... In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product. …***The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute***. … [Emphasis added.]"[7]

- "Documents produced by Defendant generic manufacturers show that they are aware of the AWPs reported by their competitors and of the actual sales price of their generic competitors and that they manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. Each Defendant generic maker or distributor competes by inflating its AWP and thereby inflating the median AWP. The natural and expected result of this 'leap frogging' of increasing AWPs is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs."[8]

- "Thus, each Defendant concealed that (i) its AWPs were highly-inflated (and were inflated solely to cause Plaintiffs and the Class to overpay for the AWPIDs), (ii) it was manipulating the AWPs of the AWPIDs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the AWPIDs as they were sold to providers and others."[9]

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[5] "Average Wholesale Price Litigation Liability Report of Dr. Meredith Rosenthal," December 15, 2005, p. 14.

[6] "Average Wholesale Price Litigation Liability Report of Dr. Meredith Rosenthal," December 15, 2005, p. 20.

[7] "Third Amended Master Consolidated Class Action Complaint Amended to Comply with Court's Class Certification Order," pp. 47-48, ¶ 170.

[8] "Third Amended Master Consolidated Class Action Complaint Amended to Comply with Court's Class Certification Order," p. 56, ¶ 203.

[9] "Third Amended Master Consolidated Class Action Complaint Amended to Comply with Court's Class Certification Order," p. 60, ¶ 212.

- "As set forth above, The Schering Plough Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other 'off invoice' rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class."[10]

- "Given the distribution revealed by contracts and deponents, which reflect the understanding of the market in the early 1990s, the allegations in this matter can be visually presented in Figure 1.B. Over the Class Period, drug manufacturers are alleged to have artificially inflated the AWP to AWP_{ai}, thereby increasing the spread relative to the actual AAC or the actual ASP."[11]

- "The extent to which the AWP scheme caused injury and damages was determined by the extent to which the AWP was inflated. The extent to which the AWP was inflated in turn increased the incentives to those entities moving market share."[12]

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[10] "Third Amended Master Consolidated Class Action Complaint Amended to Comply with Court's Class Certification Order," p. 184, ¶ 502.

[11] "Rebuttal Declaration of Dr. Raymond S. Hartman In Support of Plaintiff's Motion for Class Certification," December 16, 2004, p. 66.

[12] "Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification," September 3, 2004, p. 1.